SEP 0 1 2005 K052074

JSZ-Stat-Tree, JSZ-Stat-Or,
JSZ-Wet-Tree, JSZ-Wet Or 510(k)

SUMMARY, FREEDOM OF INFORMATION

JSZ-STAT-TREE, AND JSZ-STAT-OR,
CLEANING, DISINFECTING AND STORING SOLUTIONS;

AND JSZ-WET-TREE AND JSZ-WET-OR,
WETTING, LUBRICATING AND REWETTING SOLUTIONS

FOR RIGID GAS PERMEABLE CONTACT LENSES

1. Common/Usual Names	JSZ-Stat-Tree, and JSZ-Stat-Or, Cleaning, Disinfecting and Storing Solutions; and JSZ-Wet-Tree and JSZ-Wet-Or, Wetting, Lubricating and Rewetting Solutions
2. Trade/Proprietary	JSZ-Stat-Tree, and JSZ-Stat-Or, Cleaning, Disinfecting and Storing Solutions; and JSZ-Wet-Tree and JSZ-Wet-Or, Wetting, Lubricating and Rewetting Solutions
3. FDA Classification	Class II (Performance Standards) 21 CFR 886.5918 Rigid Gas Permeable (RGP) contact lens solutions
4. Performance standards	None established under section 514

5. Substantial equivalence

These products are substantially equivalent to several currently marketed products, such as DeStat-3 and Destat 4 Cleaning, Disinfecting and Storage Solutions, Stay-Wet 3 and Stay-Wet 4 Wetting and Rewtting Drops, Optimum by Lobob Cleaning, Disinfecting and Storage Solution, Wetting and Rewetting Drops, and Claris Cleaning and Soaking Solution.

6. Indications for Use

JSZ-Stat-Tree Cleaning, Disinfecting, Storage Solution is indicated for use in the cleaning, chemical disinfection and storage of fluoro/silicone acrylate and silicone acrylate (RGP) contact lenses.
JSZ-Stat-Or Cleaning, Disinfecting, Storage Solution is indicated for use in the cleaning, chemical disinfection and storage of fluoro/silicone acrylate and silicone acrylate (RGP) contact lenses.
JSZ-Wet-Tree Wetting. Lubricating, Rewetting Drops are indicated for use to wet fluoro/silicone acrylate and silicone acrylate rigid gas permeable (RGP) contact lenses prior to lens insertion and to rewet and lubricate the lens while on the eye.
JSZ-Wet-Or Wetting. Lubricating, Rewetting Drops are indicated for use to wet fluoro/silicone acrylate and silicone acrylate rigid gas permeable (RGP) contact lenses prior to lens insertion and to rewet and lubricate the lens while on the eye.

SUMMARY

Contained in this submission are comparisons of the products to the predicate devices, information on the chemistry and manufacturing, toxicology and microbiology. Because the predicate devices, with identical formulations, have been previously approved for market, and have been marketed over the last decade, no clinical data is included in this submission.

I. Chemistry

The JSZ-Stat-Tree/JSZ-Wet-Tree and the JSZ-Stat-Or/JSZ-Wet-Or systems were compatible with all groups of RGP lenses. Both JSZ-Stat-Tree and JSZ-Stat-Or were shown to be effective daily cleaners.

II. Toxicology

The toxicological testing of the the JSZ-Stat-Tree/JSZ-Wet-Tree, and JSZ-Stat-Or/,JSZ-Wet-Or systems for the cleaning, disinfecting and storing, and wetting, lubricating and rewetting of rigid gas permeable lenses is summarized below.

Test	DeStat-3/DeStat-4	Stay-Wet-3/Stay-Wet 4
Cytotoxicity	NA[a]	passed
Acute Oral Toxicity	passed	passed
Ocular Irritation (21d rabbit)	passed[b]	
Ocular Irritation (72hr rabbit)	passed[b]	
Anesthetic Effect	NA[a]	passed
Guinea Pig Maximization	passed[c]	
Corneal Epithelial Wound Healing	passed[c]	
Corneal Penetration	passed[c]	

[a] NA - test not applicable to cleaning solutions
[b] Test used JSZ-Stat-Tree/JSZ-Wet-Tree, or JSZ-Stat-Or/JSZ-Wet-Or
[c] Tests on benzyl alcohol

III. Microbiology

The microbiological testing of the the JSZ-Stat-Tree/JSZ-Wet-Tree, and JSZ-Stat-Or/,JSZ-Wet-Or systems for the cleaning, disinfecting and storing, and wetting, lubricating and rewetting of rigid gas permeable lenses is summarized below.

JSZ-Stat-Tree, JSZ-Stat-Or,
JSZ-Wet-Tree, JSZ-Wet Or 510(k)

Test	JSZ-Stat-Tree	JSZ-Stat-Or	JSZ-Wet-Tree	JSZ-Wet-Or
Disinfection Efficacy (microbial, viral)	passed	passed	NA[a]	NA
Neutralizer Efficacy	passed	passed	NA	NA
Preservative Efficacy	passed	passed	passed	passed
Sterility/Stability[b]	passed	passed	passed	passed

[a] NA - Not applicable to rewetting solutions
[b] Protocol for real-time stability of JSZ products included

IV. Clinical Studies

Clinical data is not required for solutions using the same active ingredients at the same concentrations as currently marketed products.

V. Substantial Equivalence

The solutions are identical to the DeStat-3, DeStat-4, Stay-Wet 3, and Stay-Wet-4 solutions previously approved, and substantially equivalent to the Optimum by Lobob Cleaning, Disinfecting and Storage Solution, Optimum by Lobob Wetting and Rewetting Drops, and Claris by Menicon Cleaning and Soaking Solution.

VI. Manufacturing

Manufacturing details are included in the manufacturing section.

VII. Shelf Life

The shelf life is assumed to be the same as in the predicate filings and a protocol for on-going real time shelf-life is included.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 0 1 2005

John Szabocsik, Ph.D.
President
SZABOCSIK AND ASSOCIATES
203 North Wabash Avenue
Chicago, Illinois 60601

Re: K052074
Trade/Device Name: JSZ-Stat-Tree, and JSZ-Stat-Or, Cleaning, Disinfecting and Storing Solutions; and JSZ-Wet-Tree and JSZ-Wet-Or, Wetting, Lubricating and Rewetting Solutions
Regulation Number: 21 CFR 886.5918
Regulation Name: Rigid Gas Permeable (RGP) contact lens solutions
Regulatory Class: Class II
Product Code: MRC
Dated: July 29, 2005
Received: August 1, 2005

Dear Dr. Szabocsik :

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 827-8910. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

David M. Whipple
Acting Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

JSZ-Stat-Tree, JSZ-Stat-Or,
JSZ-Wet-Tree, JSZ-Wet Or 510(k)

510(k) NUMBER (IF KNOWN) K052074

DEVICE NAME **JSZ-Stat-Tree Cleaning, Disinfecting, Storage Solution**
JSZ-Stat-Or Cleaning, Disinfecting, Storage Solution

JSZ-Wet-Tree Wetting. Lubricating, Rewetting Drops
JSZ-Wet-Or Wetting. Lubricating, Rewetting Drops.

INDICATIONS FOR USE

JSZ-Stat-Tree Cleaning, Disinfecting, Storage Solution is indicated for use in the cleaning, chemical disinfection and storage of fluoro/silicone acrylate and silicone acrylate (RGP) contact lenses.

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use __ OR Over-The-Counter-Use ✓ (Per 21 CFR 801.109)
(Optional Format 1-2-96)

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K052074